

## REMARKS

The Official Action of November 29, 2004 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Applicants once again affirm their election of the product claims of Group I (claims 1-5). Upon allowance of a product claim, Applicants respectfully request rejoinder of any method claims that depend from the allowed product claim in accordance with the provisions of MPEP Section 821.04.

The Examiner has objected to the specification because it allegedly contains embedded hyperlinks or other form of browser-executable code, and has requested deletion thereof. Applicants respectfully submit that deletion of the alleged hyperlinks is not required where, as here, Applicants do not intend to have these hyperlinks be active links. In accordance with MPEP Section 608.01, Applicants respectfully request that the Examiner withdraw the objection to these hyperlinks and, at such time as the application is allowed, to disable these hyperlinks when preparing the text to be loaded onto the USPTO web database.

The claims have been amended to remove the bases for the objection at paragraph 4b of the Official Action and the rejections at paragraphs 6A-F of the Official Action. In particular, claim 1 has been rewritten as new claim 17, which expressly recites a “primer pair” and identifies the recited sequences by “SEQ ID NO”. Claim 2 has been canceled. Claims 3-

5 have been rewritten as mixture (“kit”) claims 18-20 and are free of the informalities noted by the Examiner. All claims as amended are respectfully believed to be free of the bases for rejection noted by the Examiner and are otherwise believed to satisfy the dictates of 35 USC 112, second paragraph.

New claims 21-26 have been added more completely to define the subject matter which Applicants regard as their invention. These claims use the “consisting of” or “consisting essentially of” transitional to limit the recited sequences in accordance with the definitions provided in MPEP Section 2111.03. Claims 21 and 22 are directed to the recited universal primer pair, whereas each of claims 23-26 is directed to individual of the primers recited in the primer pair.

The Examiner had rejected claims 1 and 5 under 35 USC 102(b) as allegedly being anticipated by Matthee et al. The Examiner had rejected claims 1-5 under USC 103(a) as allegedly being unpatentable over Matthee et al in view of Kocher et al. Applicants respectfully traverse these rejections.

From the Examiner’s comments, it is respectfully believed that the basis for the 102 rejection of the claims was the use in the claims as filed of the “comprising” transitional, which the Examiner considered to read on any nucleic acid sequence comprising the recited sequences. Applicants respectfully submit that this rejection has now been obviated by the amendment of the claims. All of the claims now use a transitional which at least partially closes

the claim to the full length sequences described in the cited reference.

With respect to the rejection under 35 USC 103(a), Applicants respectfully note that this is a situation wherein the claimed species of DNA molecule is not shown or suggested in the genus encompassed by the prior art references. As discussed in MPEP Section 2144.08, in order for there to be an alleged *prima facie* case of obviousness under these circumstances, there would have to have been a motivation in the reference(s) to select the claimed DNA molecules from the vast number of possible DNA fragments subsumed by the genus described in the reference. There is no such motivation in the parent case.

The claimed primers when used in combination in a polymerase chain reaction method amplify a unique segment of mitochondrial cytochrome b gene and that segment when sequenced using the same primer(s) serves as molecular signature of the species of unknown sample in question. Although the complementary sequences of the recited primers might be present (comprised) in Matthee within the gene for which they have been designed (mitochondrial cytochrome b gene in this case), this would not generate the unique molecular signature from an unknown biological sample in question to delineate its species identity. Indeed, there is no motivation in the reference to select the unique primer pair as claimed that can be used in combination in a polymerase chain reaction method to amplify a specific segment of the gene (segment spanning the region 398-869 of mitochondrial cytochrome b gene in this case). Matthee et. al. (1998) do not show or suggest anything about the power of this gene when combined with the claimed primers. Accordingly Matthee et al cannot be said even to

set forth a *prima facie* case of obviousness for the invention as claimed.

In paragraph 8 of the Official Action, the examiner mentions that Matthee et. al. teach a sequence of nucleic acids of claim 1 and 5 of mitochondrial DNA cytochrome b gene comprising (having) the sequence of the recited primers. However, Matthee et al simply used the sequences of cytochrome b gene amplified from known animal specimen of family bovidae to investigate the Phylogenetic relationships amongst them. Respectfully, this would not provide a motivation for selecting the claimed universal primers. Generating the nucleotide sequences from biological specimen of known animal species by the PCR method to investigate the molecular relationships amongst them (as done by Matthee et. al.) or to study the evolution of those sequences over a period of time (as done by Kocher et. al.) is completely different from delineating the molecular signatures from a biological sample of unknown origin, as may be achieved with the claimed primers. Neither Matthee et. al. nor Kocher et. al. describe anything about such powers of their primers in their studies and neither suggest what primers could be isolated to achieve this.

In paragraph 8, the Examiner also mentions that Matthee et. al. found in their study that there is not significant heterogeneity between taxa and there are variations within the species. Again, this would not provide any motivation to select the claimed primers from any genus of DNA molecules described in the reference. Moreover, while indicating that there is no significant heterogeneity between taxa of family bovidae, Matthee et al simply mean that different lineages of family bovidae evolve with significantly similar rate i.e the rate constancy of

the evolution of different lineages of family bovidae is not rejected statistically. They did this analysis to justify that the Phylogenetic relationship they obtained in their study amongst the species of family bovidae are not mis-labeled because of the differential rate of evolution of different taxa under investigation. There is not anything in this observation that would provide a motivation to isolate the claimed primer pair.

Polymerase chain reaction, popularly known as PCR, is basically an in vitro reaction for amplifying a specific stretch of nucleic acid from a complex mixture of nucleic acids (even from the mixture of an entire genome of an organism). It uses a thermostable polymerase and a pair of short oligonucleotides 'the primers' which identify and anneal to the complementary sequence of nucleic acid if it is present in the complex mixture of nucleic acids i.e. 'the target sequence'. Once the pair of primers, i.e. the forward and reverse primers, meet their complementary sequences in a complex mixture of nucleic acid (i.e. the complex mixture of an entire genome of a biological sample of unknown species origin in the present case) and face each other in a specific orientation, the intervening sequence is amplified millions of times.

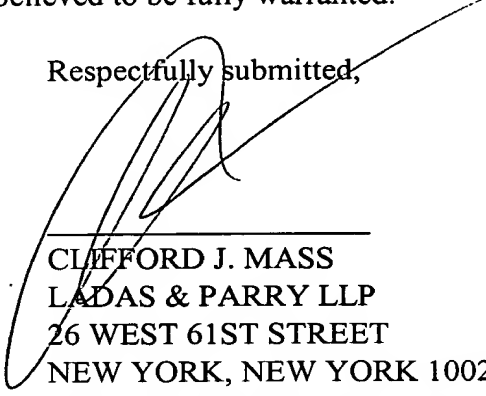
The success of this reaction depends on several critical factors, which have been addressed in detail in the present specification. One of the most important factors determining the success of this reaction is the sequence of the forward and reverse primers. This reaction, i.e. the polymerase chain reaction (PCR), when utilizing the powers of unique pair of primers used in the reaction, might address many complicated questions of biology, such as insights into the rate of evolution of various species (as described by Kocher et.al) or the Phylogenetic

relationships amongst the species (as described by Matthee et. al. 1998). However, the polymerase chain reaction (PCR) by itself cannot do anything if it is not powered with a unique pair of primer to solve a particular problem.

The problem solved by the claimed invention was 'how to establish the identity of a biological sample of an unknown origin such as drop of blood, piece of skin or bunch of hair beyond a reasonable doubt over the morphological and biochemical approaches which are still in use in most wildlife forensic laboratories in existence. Since no one, including Kocher et al or Matthee et. al., understood that the universal primers as claimed could be used to decode the molecular signatures from a biological sample of unknown species origin, there would have been no motivation, absent the hindsight the present specification to isolate the claimed primers. The present specification describes how beautifully these hidden signatures can be delineated by the claimed primers to address the question of the identity of unknown biological samples. Neither Matthee et al nor Kocher et al recognized that, if one knew the sequence of a specific region of cytochrome b gene (the region identified in the specification, i.e. the region spanning nucleotide position 398-869 in mitochondrial cytochrome b gene)) one could determine the species of the unknown biological sample in question. Moreover, neither provide any motivation to select the claimed universal primer sequences from any genus of sequences described therein.

In view of the above, it is respectfully submitted that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



---

CLIFFORD J. MASS  
LADAS & PARRY LLP  
26 WEST 61ST STREET  
NEW YORK, NEW YORK 10023  
REG. NO.30,086(212)708-1890